

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

Plaintiff,

v.

MCNEIL-PPC, INC., a corporation,
VERONICA CRUZ, and HAKAN ERDEMIR,
individuals,

Defendants.

Civil Action No. _____

**PLAINTIFF, UNITED STATES OF AMERICA'S UNCONTESTED MOTION FOR
ENTRY OF CONSENT DECREE**

Plaintiff, the United States of America moves this Court to enter the proposed Consent Decree of Permanent Injunction filed with the Court on March 10, 2011.

In support of this Uncontested Motion, the United States of America states as follows:

1. On March 10, 2011, the United States filed a Complaint for permanent injunctive relief against Defendants in this Court as authorized by 21 U.S.C. § 332(a). The Complaint alleges that Defendants violate the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, by introducing or delivering, or causing to be introduced or delivered, adulterated drugs into interstate commerce in violation of 21 U.S.C. § 331(a) and violating 21 U.S.C. § 331(k) by causing drugs held for sale (after shipment of one or more of their components in interstate commerce) to become adulterated.

2. The Complaint further alleges that FDA inspections of two of Defendants' manufacturing facilities in Pennsylvania and a third in Puerto Rico established that drugs

manufactured by Defendants at the facilities are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs and components are not in compliance with Current Good Manufacturing Practice requirements for drugs. See 21 C.F.R. §§ 210, 211.

3. Each Defendant to be enjoined has consented to entry of the proposed Consent Decree without contest and without admitting or denying the allegations in the Complaint.

4. The United States, having concluded that entry of the Consent Decree is in the public interest, also consents to entry of the Consent Decree to resolve the claims asserted in the Complaint.

5. The Consent Decree is the product of complex negotiations between the parties and sophisticated counsel. It contains extensive provisions to promote Defendants' compliance with the FDCA and its associated regulations, including significant ongoing supervision of McNEIL's manufacturing operations at the subject facilities.

6. "Resolution of litigation by voluntary settlement is favored because the parties and the public avoid the time and expense of taking the case to trial. This policy is particularly strong where the government has brought suit to obtain compliance with the law and determines that settlement of dispute by consent decree is in the public interest." United States v. Atlas Minerals & Chems., Inc., 851 F. Supp. 639, 648 (E.D. Pa. 1994) (citing Pennwalt Corp v. Plough Inc., 676 F.2d 77, 80 (3d Cir. 1982) and United States v. Cannons Eng'g Corp., 899 F.2d 79, 84 (1st Cir. 1990)).

7. Moreover, "the balance of the competing interests must initially be left to the discretion of the Attorney General when the United States brings the action, especially when the

Justice Department negotiated the consent decree on behalf of an agency specially expert in the field.” Id. (internal quotation omitted).

8. All of the parties agree that the negotiated consent decree is lawful, reasonable, fair, and consistent with the purposes that the FDCA is intended to serve. *See id.*

9. Defendants do not contest this Motion.


10. Accordingly, the United States respectfully requests that Court enter the proposed Consent Decree.


Dated this 10th day of March, 2011.

Respectfully submitted,

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